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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,349	08/19/2003	Robert Seid	2300-1357.10 (PP01357.124	3803

27476 7590 10/13/2006

NOVARTIS VACCINES AND DIAGNOSTICS INC.
CORPORATE INTELLECTUAL PROPERTY R338
P.O. BOX 8097
Emeryville, CA 94662-8097

EXAMINER	
DEVI, SARVAMANGALA J N	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Interview Summary	Application No.	Applicant(s)	
	10/643,349	SEID, ROBERT	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

All participants (applicant, applicant's representative, PTO personnel):

(1) *S. Devi (PTO)*. (3) *Helen Lee*.

(2) *Amy Hessler*. (4)_____.

Date of Interview: *05 October 2006*.

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☒ Yes e)☐ No.
If Yes, brief description: *Applicants' draft amendment sent in 10/03/06 (see attachment)*.

Claim(s) discussed: *All of record, claim 31 in particular*.

Identification of prior art discussed: _____.

Agreement with respect to the claims f)☐ was reached. g)☒ was not reached. h)☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *The pending new matter and ODP rejections were discussed. Applicants were informed that claim 31, as proposed in the draft amendment, is drawn to a product that is distinct from the one that has been examined thus far in this application. Applicants would consider submitting a terminal disclaimer and canceling some claims*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

SD - 10/05/06
S. DEVI, PH.D.
PRIMARY EXAMINER

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

_____
Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)
In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

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FACSIMILE COVER SHEET

TO: Examiner S. Devi, PhD

Date: 3 October 2006

Fax No. 571-273-0854

FROM: Amy Hessler

Number of Pages: 7
(Including cover page)

RE: **U.S. Patent Application Serial No. 10/643,349**
Filing Date: 08/19/2003; Inventor: Robert Seid
For: NEISSERIA MENINGITIDIS SEROGROUP B GLYCOCONJUGATES AND METHODS OF USING THE SAME
Group Art Unit No. 1645
Confirmation no. 3803
Atty. Docket No.: 2300-1357.10 (PP01357.124)

As requested, please find attached a draft amendment for our phone interview on Thursday October 5, 2006 at 1:00 P.M. EST.

Please contact Amy Hessler at (510) 923-3833 if you have any problems receiving this transmission.

DRAFT

USSN: 10/643,349
Atty. Dkt. No.: PP001357.0124

PATENT

DRAFT
Not for entry
For discussion purposes only

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: Seid	Examiner: S. Devi
Serial No.: 10/643,349	Group Art Unit: 1645
Filing Date: August 19, 2003	Confirmation No.: 3803
Title: NEISSERIA MENINGITIDIS SEROGROUP B GLYCOCONJUGATES AND METHODS OF USING THE SAME	

DRAFT AMENDMENT UNDER 37 C.F.R. §1.116

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

Sir:

This Amendment under 37 C.F.R.§ 1.116 is being filed in response to the Office Action from the U.S. Patent and Trademark Office on July 24, 2006.

Amendments to the Claims are reflected in the listing of claims, which begins on page 2 of this paper.

Remarks begin on page 5 of this paper.

DRAFT

AMENDMENTS TO THE CLAIMS

This listing of the claims will replace all prior versions, and listings, of claims in the application.

1-30. (Canceled)

31. (Currently amended): A substantially homogenous sized *Neisseria meningitidis* serogroup B capsular oligosaccharide (MenB OS) glycoconjugate produced by a method comprising:

(a) providing a heterogenous population of MenB OS in which sialic acid residue N-acetyl groups are replaced with N-C_3-C_8 acyl groups;

(b) obtaining a substantially homogenous sized group of MenB OS from the population of step (a) wherein said group of MenB OS has an average degree of polymerization (Dp) of about 10 to 20;

(c) covalently attaching a C3-C16 long-chain aliphatic lipid to the ~~nonreducing~~ reducing end of the MenB OS obtained in step (b);

(d) introducing a reactive group at the ~~reducing~~ nonreducing end of the MenB OS obtained in step (c) to provide single end-activated MenB OS of said DP; and

(e) covalently attaching the single end-activated MenB OS obtained in step (d) to a protein carrier molecule to provide the substantially homogenous sized MenB OS glycoconjugate.

32. (Previously presented): A substantially homogenous sized *Neisseria meningitidis* serogroup B capsular oligosaccharide (MenB OS)/CRM_{197} toxoid glycoconjugate produced by a method comprising:

(a) providing a heterogenous population of MenB OS in which sialic acid residue N-acetyl groups are replaced with saturated N-propionyl groups;

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(b) obtaining a substantially homogenous sized group of MenB OS from the population of step (a) wherein said MenB OS have an average degree of polymerization (Dp) of about 12 to 18;

(c) covalently attaching a C3-C16 long-chain aliphatic lipid to the nonreducing end of the MenB OS obtained in step (b);

(d) introducing a reactive group at the reducing end of the MenB OS obtained in step (b) to provide single end-activated MenB OS of said DP; and

(e) covalently attaching the single end-activated MenB OS obtained in step (d) to a CRM_{197} bacterial toxoid carrier molecule to provide the substantially homogenous sized MenB OS/CRM_{197} toxoid glycoconjugate.

33-42. (Canceled)

43. (Previously presented): The glycoconjugate of claim 31, wherein the reactive group introduced in step (d) comprises an active ester group.

44. (Canceled)

45. (Previously presented): The glycoconjugate of claim 31, wherein the carrier molecule is a bacterial toxoid.

46. (Previously presented): The glycoconjugate of claim 45, wherein the bacterial toxoid is a nontoxic mutant bacterial toxoid.

47. (Previously presented): The glycoconjugate of claim 31, wherein the MenB OS has an average degree of polymerization (Dp) of about 12 to about 18.

48-49. (Canceled)

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50. (Previously presented): A substantially homogenous sized *Neisseria meningitidis* serogroup B capsular oligosaccharide (MenB OS) glycoconjugate produced by a method comprising:

(a) providing a heterogenous population of MenB OS in which sialic acid residue N-acetyl groups are replaced with N-C_3-C_8 acyl groups;

(b) obtaining a substantially homogenous sized group of MenB OS from the population of step (a) wherein said group of MenB OS has an average degree of polymerization (Dp) of about 10 to 20;

(c) introducing a reactive group at the reducing end of the MenB OS obtained in step (b) to provide single end-activated MenB OS of said DP; and

(d) covalently attaching the single end-activated MenB OS obtained in step (c) to a protein carrier molecule to provide the substantially homogenous sized MenB OS glycoconjugate.

51. (Previously presented): The glycoconjugate of claim 50, wherein the reactive group introduced in step (c) comprises an active ester group.

52. (Previously presented): The glycoconjugate of claim 50, wherein the protein carrier molecule is a bacterial toxoid.

53. (Previously presented): The glycoconjugate of claim 52, wherein the bacterial toxoid is a nontoxic mutant bacterial toxoid.

54. (Previously presented): The glycoconjugate of claim 53, wherein the nontoxic mutant bacterial toxoid is CRM197.

55. (Previously presented): The glycoconjugate of claim 50, wherein the MenB OS has an average degree of polymerization (Dp) of about 12 to about 18.

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REMARKS

35 U.S.C. § 112, first paragraph, New Matter

Claim 31 and those dependent therefrom have been rejected under 35 U.S.C. § 112, first paragraph as allegedly containing new matter.

In an effort to advance prosecution, step (c) of claim 31 has been amended to specify that the C3-C16 long-chain aliphatic lipid be covalently attached to the *reducing* end of the MenB OS obtained in step (b). Step (d) of claim 31 has been amended to specify that the reactive group be introduced at the *nonreducing* end of the MenB OS obtained in step (c).

Support for the claim amendments is found throughout the specification including, for example, at page 5, lines 3-5; and page 14 lines 14-17. No new matter has been added.

Amendment of the claims is made without prejudice, without intent to abandon any originally claimed subject matter, and without intent to acquiesce in any rejection of record. Applicant expressly reserves the right to file one or more continuing applications hereof containing the canceled or unamended claims.

Obviousness-Type Double Patenting

Applicant reiterates the request that the requirement for submission of a Terminal Disclaimer with respect to U.S. Patent No. 6,638513 be held in abeyance until there is an indication of allowable subject matter in the present application.

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USSN: 10/643,349
Atty. Dkt. No.: PP001357.0124

CONCLUSION

In light of the claim amendments and above remarks, Applicant submits that the present application is in condition for allowance.

Respectfully submitted,

By:___DRAFT_____
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